K123978

CAPSTONE® L Spinal System
510(k) Summary
December 21, 2012

APR 9 2013

I.	**Company:**	Medtronic Sofamor Danek 1800 Pyramid Place Memphis, TN 38132 Telephone: (901) 396-3133 FAX: (901) 346-9738
II.	**Contact:**	Lauren Kamer Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	CAPSTONE® L Spinal System
IV.	**Common Name:**	Intervertebral Body Fusion Device with Bone Graft, Lumbar
V.	**Classification Name:**	Intervertebral Body Fusion Device (21 CFR 888.3080)
	Class:	II
	Product Code:	MAX

VI. Product Description

The CAPSTONE® L Spinal System consists of spacers of various widths and heights made of PEEK with tantalum markers. The spacers can be inserted between two lumbar or lumbo-sacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The implant has non-lordotic and 6° lordotic options. The superior and inferior surfaces of the implant are designed with teeth that interact with the surface of the vertebral endplates to aid in resisting expulsion. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The implants are provided sterile by gamma irradiation, and are to be used with supplemental fixation. CAPSTONE® L Spinal System is used with new reusable instrumentation that enables the surgeon to implant the devices via a lateral approach.

VII. Indications for Use

The CAPSTONE® L Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CAPSTONE® L Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

These indications for use are identical to those for the predicate CLYDESDALE® Spinal System (K100175, SE Jun 2, 2010).

VIII. Summary of Technological Characteristics

The CAPSTONE® L Spinal System has the same fundamental scientific technology as the predicate CLYDESDALE® Spinal System. Like CLYDESDALE® Spinal System implants, CAPSTONE® L Spinal System implants are interbody fusion devices manufactured from PEEK per ASTM F2026, and include tantalum markers per ASTM F560 for imaging purposes. The implants have a non-lordotic and a 6° lordotic option, and the superior and inferior surfaces are designed with teeth that interact with the surface of the vertebral endplates to aid in resisting expulsion. The implants are designed with a bullet-nosed tip to aid in distraction and insertion into the disc space, and their hollow geometry allows them to be packed with autogenous bone graft. The implants are provided sterile by gamma irradiation, and are to be used with supplemental fixation. CAPSTONE® L Spinal System implants may be implanted via a minimally invasive lateral surgical approach.

IX. Identification of the Legally Marketed Predicate Device Used to Claim Substantial Equivalence

In order to demonstrate substantial equivalence to legally marketed predicate devices, CLYDESDALE® Spinal System (K100175, SE Jun 2, 2010) is used as the primary predicate for intended use and fundamental scientific technology. CLYDESDALE® Spinal System 510(k)s K112405, SE Nov 21, 2011; K113528, SE Dec 20, 2011; and K122591, Sep 18, 2012, are the labeling predicates for this submission.

CAPSTONE® Spinal System (K073291, SE Apr 24, 2008) is additionally used as a predicate for this submission to demonstrate that the additional size options and mechanical performance of the subject device are substantially equivalent to other legally marketed interbody fusion devices.

X. Brief Discussion of the Non-Clinical Tests Submitted

An assessment of the device modifications was completed in accordance with Medtronic design control processes.

Mechanical testing was conducted according to FDA guidance document, "Class II Special Controls Guidance Document: Intervertebral Body Fusion Devices", and the following standards:

- ASTM F2077: Test Methods for Intervertebral Body Fusion Devices
    - Static Compression
    - Static Compression-Shear
    - Dynamic Compression
    - Dynamic Compression-Shear

- ASTM F2267: Standard Test Method for Measuring Load Induced Subsidence of the Intervertebral Body Fusion Device under Static Axial Compression

Expulsion testing was also conducted.

All mechanical testing met the predetermined acceptance criteria.

XI. Conclusions Drawn from the Non-Clinical Tests

A risk analysis was completed. Based on the risk analysis, mechanical testing, and additional supporting documentation provided in this premarket notification, the subject CAPSTONE® L Spinal System demonstrates substantial equivalence to the predicates CLYDESDALE® Spinal System (K100175, SE Jun 2, 2010; K112405, SE Nov 21, 2011; K113528, SE Dec 20, 2011; and K122591, Sep 18, 2012) and CAPSTONE® Spinal System (K073291, SE Apr 24, 2008).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2013

Medtronic Sofamor Danek USA
% Ms. Lauren Kamer
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K123978
Trade/Device Name: CAPSTONE® L Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 8, 2013
Received: March 11, 2013

Dear Ms. Kamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123978

Device Name: CAPSTONE® L Spinal System

Indications for Use:

The CAPSTONE® L Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CAPSTONE® L Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH/ODE

Anton E. Dmitriev, PhD
Division of Orthopedic Devices